Test Report

(Electronic version)

Verification Website: www.gttc.net.cn

Verification Code: LTEP-9322-34

No:20R001308 Issue Date: 2020-05-28

Applicant: SHANDONG INTCO MEDICAL PRODUCTS CO., LTD.
Address: QIWANG ROAD NO. 9888, NAOSHAN INDUSTRIAL PARK, QINGZHOU, SHANGDONG, CHINA, 262500

Information confirmed by applicant:

Medical face mask

Quantity:eighty pieces

Standard Adopted:

EN 14683:2019+AC:2019 <Medical face masks-Requirements and test methods>

Date Received/Date Test Started: 2020-05-13

Conclusion:

Bacterial filtration efficiency (BFE)	M
Microbial cleanliness	M
Differential pressure	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

Remark:
All the tested items are tested under the standard condition (except for indication).
Copies of the report are valid only re-stamped.
The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By: Zishan Guo

ZiShan Guo Senior Engineer

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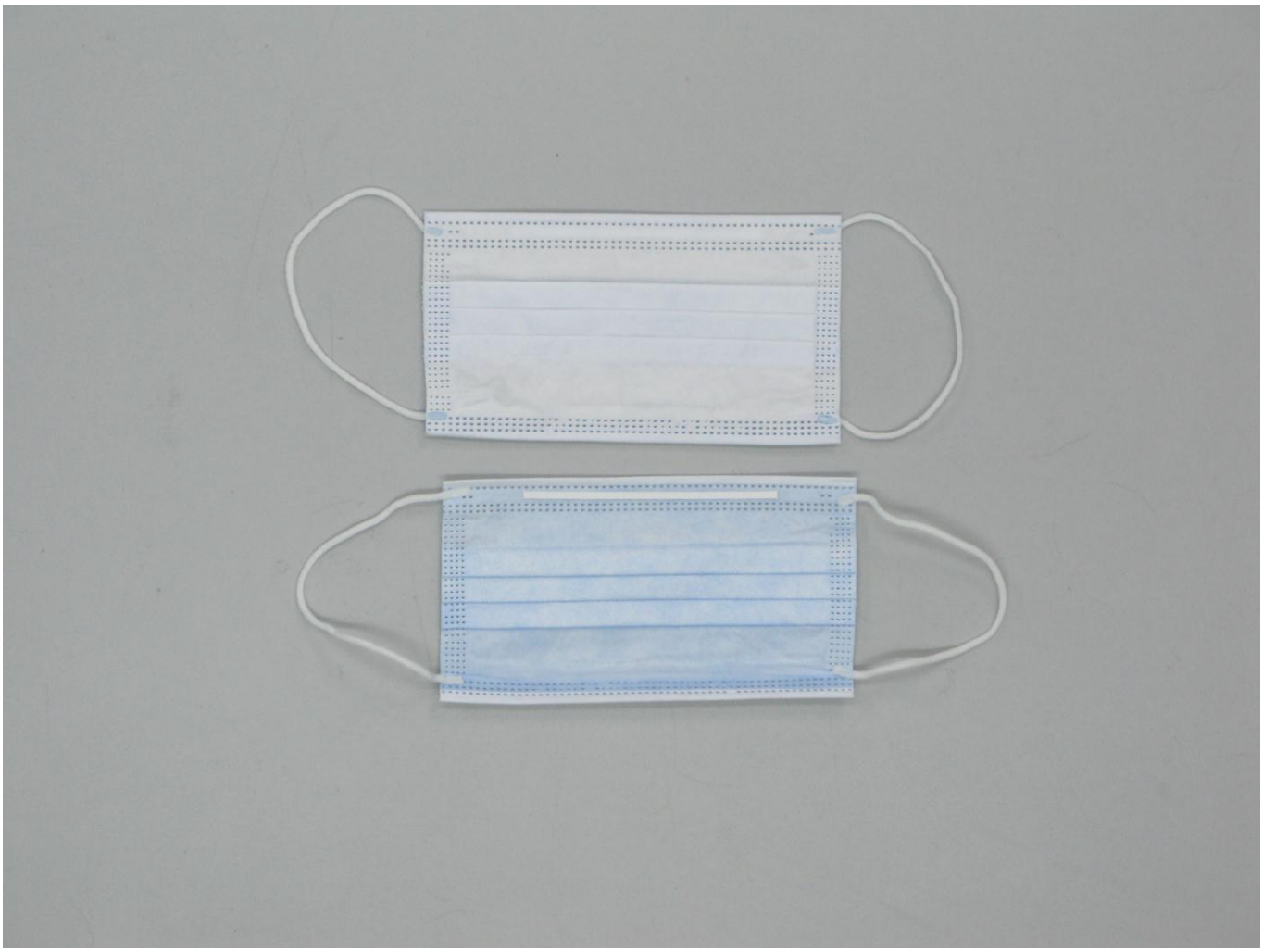

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Bacterial filtration efficiency (BFE)
Test method: EN 14683: 2019+AC: 2019 Annex B

Test principle:
A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test equipment:
Incubator
Electronic balance
Autoclave
Experimental system for bacterial filtration efficiency (BFE) of mask

The environmental conditions of the laboratory and test condition:
Total bacteria: 0 CFU/plate
Total fungi: 0 CFU/plate
Blank experiment: Aseptic growth
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Culture medium: TSA agar medium
Culture temperature: 37℃， Culture time: 48h
Test bacteria : staphylococcus aureus ATCC 6538
Concentration of bacterium: 5.0×10^5 CFU /ml
Positive control average (C): 1.9×10^3 CFU
Negative monitor count: ＜1 CFU
Test area: 49 cm^2
Dimensions of the test specimens: 15cm×15cm
Flow rate: 28.3 l/min
Pretreatment: Condition each specimen for 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Mean particle size: 3.0 μm
The medical face mask in contact with the bacterial challenge: inside

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Results:

Sample	T	BFE (%)	Requirement (%)	Classification	Conclusion
1	10	99.47	≥95 EN 14683:2019+AC:2019	Type Ⅰ	Pass
2	10	99.47			
3	8	99.58			
4	6	99.68			
5	14	99.26			

Remarks:

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$B = (C - T) / C \times 100$

where

B is bacterial filtration efficiency (BFE), %;

C is positive control average;

T is the total plate count for the test specimen.

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Microbial cleanliness
Test method: EN ISO 11737-1:2018, Membrane filtration

Test principle:
Take the required samples from the original packaging. Weigh a certain amount of sample and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l Tween 20). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) for fungi enumeration. The plates are incubated for 3 days at 30℃ and 7 days at (20 to 25)℃ for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

Test equipment:
Constant temperature incubator
Electronic balance
Pressure steam sterilizer
Biosafety cabinet

The environmental conditions of the laboratory and test condition:
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth

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Results:

Sample	Bacteria (CFU/g)	Fungi (CFU/g)	Microbial cleanliness (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
1	8	2	10	≤30 EN 14683:2019+AC:2019	Type Ⅰ	Pass
2	6	1	7			
3	10	3	13			
4	7	2	9			
5	9	2	11			

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Differential pressure

Test method: EN 14683:2019+AC:2019 Annex C

Test principle:

This procedure was performed to evaluate the differential pressure of the medical face mask material by measuring the air exchange pressure through a measured surface area at a constant air flow rate.

Test equipment:

GTTC-YLC-1 Apparatus for measuring differential pressure

The environmental conditions of the laboratory and test condition:

Air flow: 8 l/min

Test area: 4.9cm^2

Pretreatment: Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%

General location of the areas of the mask the differential measurements: specimen center

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Sample	Differential pressure (Pa/cm²)	Requirement (Pa/cm²)	Classification	Conclusion
1	24.5	＜40 EN 14683:2019+AC:2019	Type Ⅰ	Pass
2	22.9			
3	24.9			
4	24.1			
5	24.1			

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